

### **REMARKS**

This application has been reviewed in light of the Office Action dated September 26, 2003. Claims 1-26 are pending in the application. Claims 1-5 and 18-21 are amended in a manner that Applicants believe overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. Applicants submit that no new matter or issues are introduced by the amendments.

In the Office Action, claims 1-17 were rejected under 35 U.S.C. § 112. Claims 1-4 and independent claim 5, from which claims 6-17 depend, are amended in a manner believed to overcome the rejections. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-4 and 21-23 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,968,021 to Ejlersen (Ejlersen '021). However, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 21 and claims 22-23 depending therefrom, clearly and patentably distinguish over the Ejlersen '021 patent.

Referring to Figs. 1-3, the Ejlersen '021 patent discloses ribs 9 that center a connecting piece 4 with a sleeve 3. (col. 4, lines 26-31). In contrast, amended claim 1 of the present application recites "[a] needle assembly comprising: a needle hub defining an interior cavity having a distal end and at least one fin being disposed therein that intersects an interior surface of the needle hub that defines the interior cavity wherein, the at least one fin extends longitudinally a fixed distance from the distal end of the interior cavity to a proximal facing surface that engages a barrel tip of the needle assembly when disposed within the interior cavity." Amended claim 21 of the present application recites "[a] needle hub defining an interior cavity and having at least one fin that intersects an interior surface of the needle hub that defines the interior cavity, the at least one fin extending longitudinally a fixed distance from a distal end of the interior cavity to a proximal facing engagement surface disposed within the interior cavity."

The Ejlersen `021 patent in no way discloses or suggests structure as recited in amended claims 1 and 21. The Ejlersen `021 patent does not disclose, *inter alia*, a needle hub having a fin that intersects an interior surface that defines an interior cavity of the needle hub, whereby the fin extends longitudinally a fixed distance to a proximal facing engagement surface disposed within the interior cavity. Rather, the Ejlersen `021 patent shows centering ribs.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 21 and claims 22-23 depending therefrom are patentable and not obvious over the Ejlersen `021 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-4, 18 and 21-23 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,964,737 to Caizza (Caizza `737). However, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 18, amended independent claim 21 and claims 22-23 depending therefrom, clearly and patentably distinguish over the Caizza `737 patent.

Referring to FIGS. 7 and 8, the Caizza `737 patent discloses an elastic plug 34, whereby the elastic properties are critical to the disclosure to account for independence of manufacturing tolerances. (col. 6, lines 44-68). In contrast, amended claims 1 and 21 of the present application are recited above. Amended claim 18 of the present application recites, *inter alia*, “[a] needle assembly comprising... a needle hub means for engaging the barrel tip in a configuration to minimize fluid waste.”

The Caizza `737 patent in no way discloses or suggests structure as recited in amended claims 1, 18 and 21. The Caizza `737 patent does not disclose, *inter alia*, a needle hub having a fin that intersects an interior surface that defines an interior cavity of the needle hub, whereby the fin extends longitudinally a fixed distance to a proximal facing engagement surface disposed within the interior cavity. Rather, the Caizza `737 patent shows an elastic plug, the elasticity of which is critical to its operation.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 18, amended independent claim 21 and claims 22-23 depending therefrom are patentable and not obvious over the Caizza `737 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-7, 10-17 and 21-23 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,040,421 to Young (Young `421). However, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 5, claims 6, 7 and 10-17 depending therefrom, amended independent claim 21 and claims 22-23 depending therefrom, clearly and patentably distinguish over the Young `421 patent.

Referring to FIG. 6, the Young `421 patent discloses an inward radial bead 54 that locks a needle assembly 24 to a syringe barrel 10. (col. 2, lines 51-60). In contrast, amended claims 1 and 21 of the present application are recited above. Amended claim 5 of the present application recites, *inter alia*, “[a] needle assembly comprising: a needle hub... having at least one fin formed therein that intersects an interior surface of the needle hub that defines the interior cavity, the at least one fin extending longitudinally a fixed distance from a distal end of the interior cavity to a proximal facing surface; and... an elongated barrel tip... engaging the proximal facing surface of the at least one fin.”

The Young `421 patent in no way discloses or suggests structure as recited in amended claims 1, 5 and 21. The Young `421 patent does not disclose, *inter alia*, a needle hub having a fin that intersects an interior surface that defines an interior cavity of the needle hub, whereby the fin extends longitudinally a fixed distance to a proximal facing engagement surface disposed within the interior cavity.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 5, claims 6, 7 and 10-17 depending therefrom, amended independent claim 21 and claims 22-23 depending therefrom are patentable and not obvious over the Young `421 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 1-15, 17, 19 and 21-26 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,935,014 to Haber (Haber `014) in view of the Ejlersen `021 patent. Claims 1-26 were also rejected over U.S. Patent No. 5,902,270 to Jentzen (Jentzen `270) in view of the Ejlersen `021 patent. However, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 5, claims 6-17 depending therefrom, amended independent claim 18, amended independent claim 19, amended independent claim 20, amended independent claim 21 and claims 22-26 depending therefrom, clearly and patentably distinguish over the Ejlersen `021 patent in any combination with the Haber `014 patent and the Jentzen `270 patent.

Referring to FIG. 1, the Haber `014 patent discloses a locking needle assembly for a medication carpule. Referring to FIG. 11, the Jentzen `270 patent discloses a needle hub 400 that defines an inner cavity. In contrast, amended claims 1, 5, 18 and 21 of the present application are recited above. Amended claim 19 of the present application recites, *inter alia*, “[a] needle hub... having four fins formed at a distal portion thereof that intersect an interior surface of the needle hub that defines the interior cavity, each of the four fins extending longitudinally a fixed distance from the distal end of the interior cavity to a proximal facing surface. Amended claim 20 of the present application recites, *inter alia*, “[a] syringe comprising... four fins... that intersect an interior surface of the hub skirt that defines the interior cavity, each of the four fins extending longitudinally a fixed distance from the distal end of the interior cavity to a proximal facing surface... the barrel tip engaging the proximal facing surfaces of the four fins...”

The Haber `014 patent and/or the Jentzen `270 patent in no way disclose or suggest structure as recited in amended claims 1, 5, 18, 19, 20 and 21. The Haber `014 patent and the Jentzen `270 patent do not cure the deficiencies of the Ejlersen `021 patent in that the Haber `014 patent and the Jentzen `270 patent do not disclose, *inter alia*, a needle hub having a fin that intersects an interior surface that defines an interior cavity of the needle hub, whereby the fin extends longitudinally a fixed distance to a proximal facing engagement surface disposed within the interior cavity.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claims 2-4 depending therefrom, amended independent claim 5, claims 6-17 depending therefrom, amended independent claim 18, amended independent claim 19, amended independent claim 20, amended independent claim 21 and claims 22-26 depending therefrom are patentable and not obvious over the Ejlersen '021 patent in any combination with the Haber '014 patent and the Jentzen '270 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

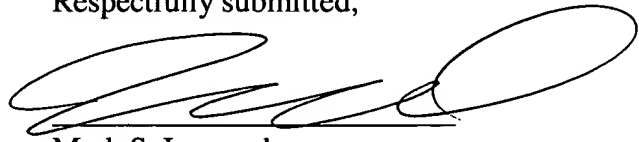
In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1-26 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fee(s) which may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

2-23-2004  
Dated:

Respectfully submitted,



Mark S. Leonardo  
Reg. No. 41,433  
Customer No. 21710  
Attorney for Applicants  
BROWN RUDNICK BERLACK ISRAELS  
Box IP, 18th Floor  
One Financial Center  
Boston, MA 02111  
Tel: 1-617-856-8145  
Fax: 1-617 856-8201